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AHCCCS MEMBER PARTICIPATION IN EXPERIMENTAL TREATMENT

<u>Description</u>. AHCCCS members who are enrolled with a Contractor, or are receiving services on a fee-for-service (FFS) basis, may participate in experimental treatment but no expenses associated with the experimental treatment are covered by AHCCCS.

Amount, Duration and Scope. If the experimental treatment provided to an AHCCCS member requires laboratory or imaging services, inpatient or other medical services, AHCCCS will not cover the added services. Coverage of care associated with complications resulting from the experimental treatment will be considered on an individual basis, but treatment of direct toxic effects are not covered. Participation in experimental treatment will not result in the loss of the member's other benefits.

The member's primary care provider must not have any financial interest in the experimental treatment and cannot accept a finder's fee for referral of a member to participate in the experiment.

Any individual expected to assess the appropriateness of services for the member cannot have a financial interest in conducting the experimental treatment, or its outcome.

Participation in a Food and Drug Administration Phase I or Phase II clinical trial must be approved by the member's Contractor, or by the AHCCCS Medical Director. If a Contractor approves participation of one or more members in an experimental trial, it must provide notice to AHCCCS/Division of Health Care Management (DHCM) and the AHCCCS Medical Director which includes assurance that the member's rights are protected and that no costs will be covered by AHCCCS. FFS member participation will be evaluated for approval by the AHCCCS Medical Director. The basis for approval will include:

1. Verification that full financial liability for the experimental treatment is taken by the researcher or the sponsor, and documentation indicates that the costs associated with the experimental treatment of direct complications or other toxic effects will not be charged to, or paid by, AHCCCS





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- 2. The experimental treatment regimen is well designed and adequate protection of the member's welfare is assured. The trial provides adequate participant information and assures participant consent, and
- 3. AHCCCS Contractor employees or network providers cannot receive fees, finder's fees or other payment for referring members or providing services as a part of the experimental treatment.



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Breast and Cervical Cancer Treatment Program

Description. Effective January 1, 2002, the Breast and Cervical Cancer Treatment Program (BCCTP) was added as a new eligibility category under AHCCCS. The Native American Breast and Cervical Cancer Treatment technical amendment that was signed into law on January 15, 2002, made it possible for Native American women to qualify for the BCCTP coverage group even if they are eligible for health services from the Indian Health Service (IHS) or a 638 Tribal Facility.

Requirements for the program specify that a woman must be screened and diagnosed as needing treatment for breast and/or cervical cancer by one of the Arizona programs of the national Breast and Cervical Cancer Early Detection Program funded by the Centers for Disease Control (CDC). These programs are

- 1. The Well Woman Healthcheck Program (WWHP), administered by the Arizona Department of Health Services (ADHS)
- 2. The Hopi Women's Health Program, and
- 3. The Navajo Nation Breast and Cervical Cancer Prevention Program.

Amount, Duration and Scope. A woman who is eligible for AHCCCS under the BCCTP receives the full range of AHCCCS covered services pursuant to Arizona Administrative Code Title 9, Chapter 22, Article 20. A woman who is eligible under this program will be enrolled with a Contractor of her choice. If she does not choose one, she will be automatically assigned to one.

Treatment Services and Eligibility.

<u>Breast Cancer</u> - Eligibility for the breast cancer program shall conclude 12 months after the last provider visit for specific treatment of the cancer, or at the end of hormonal therapy for breast cancer, whichever is later.



Treatment includes any of the following:

- 1. Surgical removal of the breast cancer
- 2. Chemotherapy
- 3. Radiation therapy, or
- 4. A treatment that, as determined by the AHCCCS Medical Director or designee, is considered the standard of care as supported by a peer-reviewed study published in a medical journal.

<u>Pre-cancerous cervical lesion(s)</u> - Eligibility for the program for a pre-cancerous cervical lesion, including moderate or severe cervical dysplasia or carcinoma in situ, shall conclude four months after the last provider visit for specific treatment for the pre-cancerous lesion(s).

Treatment includes any of the following:

- 1. Conization
- 2. Loop Electrosurgical Excision Procedure
- 3. Cryotherapy, or
- 4. A treatment that, as determined by the AHCCCS Medical Director or designee, is considered the standard of care as supported by a peer-reviewed study published in a medical journal.

<u>Cervical Cancer</u> - Treatment for cervical cancer shall conclude 12 months after the last provider visit for specific treatment of the cancer.

Treatment includes any of the following:

1. Surgery



- 2. Chemotherapy
- 3. Radiation therapy, or
- 4. A treatment that, as determined by the AHCCCS Medical Director or designee, is considered the standard of care as supported by a peer-reviewed study published in a medical journal.

<u>Metastasized Cancer</u> - A woman's eligibility and treatment under this program will continue if a metastasized cancer is found in another part of the woman's body and the metastasized cancer is a known or presumed complication of the breast or cervical cancer.

<u>Re-occurrence of the Cancer</u> - A woman will have eligibility re-established, after eligibility under this program ends, if:

The woman is screened under the WWHP program or one of the Native American programs, and

- 1. Additional breast or cervical cancer is found, or
- 2. There is re-occurrence of pre-cancerous lesion(s).

Exclusions.

A male is precluded from receiving screening and diagnostic services under the National Breast and Cervical Cancer Early Detection Program and thus is ineligible under this program.

Responsibilities.

The National Breast and Cervical Cancer Early Detection Program and staff shall:

1. Direct the woman to apply to AHCCCS for treatment if the woman's screening shows a diagnosis of breast cancer, cervical cancer or pre-cancerous cervical lesion(s). However, AHCCCS eligibility cannot be determined until a positive diagnosis is confirmed.



2. Assist the woman with a Title XIX application

A woman may apply for eligibility by completing an application for AHCCCS health insurance provided by National Breast and Cervical Cancer Early Detection Program staff. The National Breast and Cervical Cancer Early Detection Program mails the application directly to AHCCCS after receiving a positive diagnosis. A complete application contains all the information requested, including documentation verifying alien status if born outside the United States.

3. Provide AHCCCS with the diagnosis and date of diagnosis.

Responsibilities for Reporting

Background: This program is unique, in that continued eligibility is primarily determined by active treatment, and in that this program involves not only AHCCCS, but also ADHS and the CDC. The requirements for this program have created the need for special reporting by Contractors or the Native American programs as follows:

- 1. AHCCCS Division of Member Services (DMS) must be notified when active treatment has ended.
- 2. ADHS must be notified of:
 - a. Date the treatment began
 - b. Tumor size
 - c. Tumor Stage, and
 - d. Date treatment ended.



The Process for Reporting Clinical Information and Status of Treatment

- 1. AHCCCS Division of Member Services (DMS) will send forms to the appropriate Contractor that identify which women in the program require updated treatment information. The Contractor will complete the form and send it back to DMS.
- 2. For fee-for-service members, including native American program members, DMS will send forms to AHCCCS Division of Fee-for-Service Management/Prior Authorization Unit (DFSM/PA). DFSM/PA will complete the form and route it to DMS.
- 3. DMS will acquire the information they need from the forms and then send the forms on to ADHS.

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COCHLEAR IMPLANTATION

Description. AHCCCS covers medically necessary services for cochlear implantation within certain limitations as described in this policy. Cochlear implantation requires prior authorization (PA) from the member's Contractor Medical Director, or from the AHCCCS Medical Director for fee-for-service members.

Cochlear implantation provides an awareness and identification of sounds and facilitates communications for persons who have profound, sensorineural hearing loss (nerve deafness). A cochlear implant is an electronic device, surgically inserted, which converts speech and other sounds into electrical signals and sends these signals to the auditory nerve. Evaluation, counseling and education prior to surgical implant are required to determine suitability of candidates for cochlear implantation. To ensure the successful outcome for an implant recipient, post-implant rehabilitation must be provided by professionals familiar with cochlear implants.

Cochlear implantation is a covered service for members 21 years of age or older when medically necessary.

Note: Refer to Chapter 400 for information regarding cochlear implantation coverage for members under 21 years of age receiving Early and Periodic Screening, Diagnosis and Treatment (EPSDT) services.

Criteria for medical necessity include:

- 1. Diagnosis of bilateral profound sensorineural deafness, established by audiologic and medical evaluation
- 2. Prelingual/perilingual or postlingual deafness
- 3. Have an accessible cochlear lumen structurally suited to implantation, with no lesions in the auditory nerve and acoustic areas of the central nervous system, as demonstrated by CT scan or other appropriate radiologic evaluation
- 4. Absence of contraindications to surgery

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- 5. Demonstrated cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation
- 6. Failure to show improvement with hearing aid trial (hearing aids are not a covered service for members who are 21 years of age and older)
- 7. No other medical treatment is therapeutic for the individual, and
- 8. Has no functioning implant in either ear.

Prelingually/perilingually deafened adult candidates, following evaluation by the primary care physician and expert specialists, must be reviewed on an individual basis by the Contractor Medical Director. The following information must be provided for this review:

- 1. The members current history and physical examination, including information regarding previous therapy for the hearing impairment
- 2. Records documenting the members diagnosis, current medical status and plan of treatment leading to the recommendation of implantation
- 3. Current psychosocial evaluation and assessment for determining the member's suitability for implant.

<u>Amount, Duration and Scope.</u> Coverage of cochlear implantation includes the following treatment and service components:

- 1. Complete auditory testing and evaluation by an otolaryngologist, speech-language pathologist or audiologist
- 2. Pre-surgery inpatient/outpatient evaluation by a board certified otolaryngologist
- 3. Diagnostic procedures and studies, including CT scan or other appropriate radiologic evaluation, for determining candidacy suitability
- 4. Pre-operative psychosocial assessment/evaluation by psychologist or counselor

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- 5. Prosthetic device for implantation (must be non-experimental/non-investigational and be Food and Drug Administration approved and used according to labeling instructions)
- 6. Surgical implantation and related services
- 7. Post-surgical rehabilitation, education, counseling and training
- 8. Equipment maintenance, repair and replacement of external components, including replacement of the entire device if cost effective. Documentation which establishes the need to replace internal components not operating effectively must be provided at the time prior authorization is sought.

Cochlear implantation is limited to one (1) functioning implant per member. AHCCCS will not cover cochlear implantation in instances where individuals have one functioning cochlear implant. Binaural implantation is not covered.

Refer to Chapter 400 for information regarding cochlear implantation coverage for EPSDT members who are under 21 years of age.

Refer to Chapter 800 for treatment specifications, limitations and PA requirements for FFS providers.

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• HIV/AIDS TREATMENT SERVICES

<u>Description.</u> AHCCCS-covered medically necessary treatment services, rendered by qualified providers, are available for the treatment of members who have been diagnosed with HIV/AIDS. Members who are diagnosed with HIV/AIDS are also listed as members with special health care needs. Chapter 500 describes the requirements for special health care needs members. AHCCCS requires Contractors to follow the Centers for Disease Control and Prevention (CDC) guidelines for the treatment of HIV/AIDS. It is the responsibility of each Contractor to distribute these guidelines, and all updates, to HIV/AIDS treatment professionals included in their network.

As appropriate, AHCCCS shall review new technological advances in HIV/AIDS treatment, including appropriate pharmacological regimens.

This review shall include the AHCCCS Chief Medical Officer, the AHCCCS Medical Director, Contractor Medical Directors and physician experts in the treatment of HIV/AIDS.

The review may include, but is not limited to, information regarding:

- 1. Established treatment and pharmaceutical regimens
- 2. Changes in technology and treatment protocols, and
- 3. Cost implications of treatment/pharmaceutical regimens.

<u>Contractor Monitoring.</u> Contractors must develop policies and protocols that document care coordination services provided to members with HIV/AIDS. This includes monitoring of member medical care in order to ensure that medical services, medication regimens and necessary support services (i.e., transportation) are provided within specified timelines, as defined in contractual arrangements with AHCCCSA, and that these services are utilized appropriately. Support services may be coordinated with existing community resources.

In addition, Contractors must ensure that the care for members diagnosed with HIV/AIDS, who are receiving services specified by and in accordance with the guidelines set by AHCCCS, is well coordinated and managed in collaboration with the member's treating physician.

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If a conflict regarding treatment or denial of treatment arises between the member's treating physician and the Contractor Medical Director, the issue may be referred to the AHCCCS Medical Director, or designee. However, this does not preclude the member's right to file an appeal.

HIV/AIDS TREATMENT PROFESSIONALS

AHCCCS will compile, update and make available to Contractors, upon request, a listing of qualified HIV/AIDS treatment professionals (physicians, nurse practitioners and/or physician assistants). The listing will be based on information submitted by the Contractors.

A qualified HIV/AIDS treatment professional, for the purpose of this policy, is defined as a physician or practitioner who:

- 1. Is recognized in the community as having a special interest, knowledge and experience in the treatment of HIV/AIDS, and
- 2. Agrees to adhere to CDC treatment guidelines for HIV/AIDS, and
- 3. Agrees to provide primary care services and/or specialty care to AHCCCS members with HIV/AIDS, and
- 4. Demonstrates ongoing professional development by clinically managing at least five patients with HIV/AIDS during the last year, and meets one of the criteria below:
 - a. Current Board Certification or Recertification in Infectious Diseases, or
 - b. Annual completion of at least ten hours of HIV/AIDS-related Continuing Medical Education (CME), which meet the CME requirements under Arizona Administrative Code (A.A.C.) R4-16-101.

Limitations. A physician or practitioner not meeting the criteria to be a qualified HIV/AIDS treatment professional, who wishes to provide primary care services to a member with HIV/AIDS, must send documentation to the Contractor demonstrating that s/he has an established consultative relationship with a physician who meets the criteria for a qualified HIV/AIDS treatment professional as identified in this policy.

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This documentation should be maintained in the Contractor's credentialing file. These practitioners may treat members with HIV/AIDS in the following circumstances:

- In geographic areas where the incidence of members with HIV/AIDS is low, and/or where there are no available AHCCCS-registered network HIV/AIDS treatment professionals meeting this criteria, or
- When a member with HIV/AIDS chooses a provider who does not meet the criteria.

Contractor Network. Contractors must include in their individual provider networks, sufficient numbers of qualified HIV/AIDS treatment professionals (physicians, nurse practitioners and/or physician assistants). Contractors must also have policies and procedures to assure that provider requirements and standards specified in the AMPM are met. Each Contractor provider network of HIV/AIDS treatment professionals is subject to review and approval by AHCCCS, Division of Health Care Management (DHCM). Contractors must submit, annually by December 15, a list of HIV/AIDS treatment providers to AHCCCS/DHCM/Clinical Quality Management Unit (CQM) which includes:

- 1. Name and location of all qualified HIV/AIDS treatment professionals treating members with HIV/AIDS, and
- 2. For each primary care provider (PCP) treating members with HIV/AIDS who is not a qualified HIV/AIDS treatment specialist, the name and location of the consulting HIV/AIDS treatment professional.

Contractors must also notify AHCCCS/DHCM/CQM of any material change to the HIV/AIDS provider network during the year.

Contractor policies must reflect that members with HIV/AIDS have freedom of choice to select an HIV/AIDS provider from the Contractor network. If the member elects to select a PCP in the Contractor network other than one of the providers designated by the Contractor as a qualified HIV/AIDS disease treatment professional, the member must be informed that only those designated providers are authorized to render treatment regimens such as antiretroviral therapies. The selected PCP must consult with a qualified HIV/AIDS provider and follow the recommendations of the consultant in order for the treatment regimen (such as protease inhibitors) to be a covered service.

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■ LUNG VOLUME REDUCTION SURGERY (LVRS)

Amount, Duration and Scope. Effective January 1, 2004, AHCCCS covers LVRS or reduction pneumoplasty for persons with severe emphysema when performed at a facility approved by Medicare to perform this surgery and in accordance with all of the established Medicare guidelines.

The member's treating physician is responsible for providing appropriate documentation, establishing medical necessity, and verification of compliance with Medicare and AHCCCS guidelines. The documentation must be sent to the Contractor Medical Director or, for AHCCCS fee-for-service members, to the AHCCCS Medical Director, when requesting authorization.

Where possible, such surgeries, and the required pre- and post-operative therapies, will be performed at facilities approved by Medicare for LVRS reimbursement within the State of Arizona. However, AHCCCS may cover this procedure at out-of-state facilities if needed. All facilities will be required to provide proof of Medicare LVRS facility accreditation as well as meeting AHCCCS Provider Registration requirements.

AHCCCS may pay for an adult caregiver to accompany members if medically necessary when out-of-state-travel is required. Transportation, lodging and board may be covered as appropriate.

MEDICARE CRITERIA

The Centers for Medicare and Medicaid Services (CMS) have adopted the following covered and non-covered criteria regarding lung volume reduction surgery:

Covered Indications for LVRS

Covered LVRS approaches are limited to bilateral excision of damaged lung with stapling performed via median sternotomy or video-assisted thoracoscopic surgery.



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In addition, CMS has determined that LVRS is reasonable and necessary only if preceded and followed by a program of diagnostic and therapeutic services consistent with those provided in the National Emphysema Treatment Trial (NETT) and designed to maximize the patient's potential to successfully undergo and recover from surgery. The program must include a 6 to 10 week series of at least 16 and no more than 20 preoperative sessions each lasting a minimum of 2 hours. It must also include at least 6 and no more than 10 postoperative sessions, each lasting a minimum of 2 hours, within 8 to 9 weeks of the LVRS. This program must be consistent with the care plan developed by the treating physician following performance of a comprehensive evaluation of the patient's medical, psychosocial and nutritional needs, be consistent with the pre-operative and postoperative services provided in the NETT, and arranged, monitored and performed under the coordination of the facility where the surgery takes place.

CMS has determined that LVRS is reasonable and necessary only when performed at facilities that were identified by the National Heart, Lung and Blood Institute (NHLBI) as meeting the thresholds for participation in the NETT and at sites that have been approved by Medicare as lung transplant facilities.

Medicare will only consider LVRS reasonable and necessary when all of the following requirements are met and the patient satisfies all the criteria outlined as follows:



MEDICARE ELIGIBILITY CRITERIA * (AS OF AUGUST 20, 2003)

Assessment	Criteria
History and physical	Consistent with emphysema
examination	Body Mass Index (BMI) \leq 31.1 kg/m (men) or \leq 32.3 kg/m
	(women)
	Stable with ≤ 20 mg prednisone (or equivalent) daily
Radiographic	High Resolution Computer Tomography (HRCT) scan evidence of
	bilateral emphysema
Pulmonary function (pre-	Forced expiratory volume in one second (FEV1) \leq 45% predicted
rehabilitation)	$(\geq 15\% \text{ predicted if age} \geq 70 \text{ years})$
	Total Lung Capacity (TLC) ≥ 100% predicted post-bronchodilator
	Residual Volume (RV) \geq 150% predicted post-bronchodilator
Arterial blood gas level	$PCO2, \le 60 \text{ mm Hg (PCO2}, \le 55 \text{ mm Hg if one mile above sea}$
(pre-rehabilitation)	level)
	$PO2, \ge 45 \text{ mm Hg on room air } (PO2, \ge 30 \text{ mm Hg if one mile})$
	above sea level)
Cardiac assessment	Approval for surgery by cardiologist if any of the following are
	present: unstable angina; left-ventricular ejection fraction (LVEF)
	cannot be estimated from the echocardiogram; LVEF < 45%;
	dobutamine-radionuclide cardiac scan indicates coronary artery
	disease or ventricular dysfunction; arrhythmia (> 5 premature ventricular contractions (PVCs) per minute; cardiac rhythm other
	than sinus; PVCs on EKG at rest)
Surgical assessment	Approval for surgery by pulmonary physician, thoracic surgeon,
Sui gieur ussessirent	and anesthesiologist after pre-operative rehabilitation
Exercise	Post-rehabilitation 6-minute walk of ≥ 140 meters; able to complete
	3 minute unloaded pedaling in exercise tolerance test (pre- and
	post-rehabilitation)
Consent	Signed consents for screening and rehabilitation.
Smoking	Plasma cotinine level ≤ 13.7 ng/mL (or arterial carboxyhemoglobin
	\leq 2.5% if using nicotine products)
	Nonsmoking for four months prior to initial interview and
	throughout evaluation for surgery
Preoperative diagnostic	Must complete assessment and preoperative services program in
and therapeutic program	preparation for surgery
adherence	

Patients must meet all criteria to be eligible for the procedure.



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B. Non-Covered Indications for LVRS

- 1. LVRS is not covered in **any** of the following clinical circumstances:
 - a. Patient characteristics carry a high risk for perioperative morbidity and/or mortality
 - b. The disease is unsuitable for LVRS
 - c. Medical conditions or other circumstances make it likely that the patient will be unable to complete the preoperative and postoperative pulmonary diagnostic and therapeutic program required for surgery
 - d. The patient presents with FEV₁ ≤ 20% of predicted value, and either homogeneous distribution of emphysema on CT scan, **or** carbon monoxide diffusing capacity ≤ 20% of predicted value (high-risk group identified October 2001 by the NETT), or
 - e. The patient satisfies the criteria outlined above, and has severe, non-upper lobe emphysema with high exercise capacity. High exercise capacity is defined as a maximal workload at the completion of the preoperative diagnostic and therapeutic program that is above 25 watts for women and 40 watts for men (under the measurement conditions for cycle ergometry specified above).
- 2. All other indications for LVRS not otherwise specified remain non-covered.



MEDICAL FOODS

<u>Description of Benefit.</u> AHCCCS covers medical foods, within the limitations specified in this policy, for any member diagnosed with one of the following inherited metabolic conditions:

- 1. Phenylketonuria
- 2. Homocystinuria
- 3. Maple Syrup Urine Disease
- 4. Galactosemia (requires soy formula)
- 5. Beta Keto-Thiolase Deficiency
- 6. Citrullinemia
- 7. Glutaric Acidemia Type I
- 8. 3 Methylcrotonyl CoA Carboxylase Deficiency
- 9. Isovaleric Acidemia
- 10. Methylmalonic Acidemia
- 11. Propionic Acidemia
- 12. Arginosuccinic Acidemia
- 13. Tyrosinemia Type I
- 14. HMG CoA Lyase Deficiency
- 15. Cobalamin A, B, C Deficiencies



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Definitions

- 1. Medical foods means metabolic formula or modified low protein foods that are produced or manufactured specifically for persons with a qualifying metabolic disorder and that are not generally used by persons in the absence of a qualifying metabolic disorder. Soy formula is also included within the limitations set by this policy when used by persons diagnosed with galactosemia.
- 2. Metabolic nutritionist means an AHCCCS registered provider who is a registered dietitian specializing in nutritional assessment and treatment of metabolic conditions.

Conditions, Limitations and Exclusions.

- 1. The diagnosis of the member's inherited metabolic condition must be documented in the member's medical record by the primary care provider (PCP), attending physician or appropriate specialist. Documentation should also include test results used in establishing the diagnosis.
- 2. Metabolic formula and modified low protein foods must be:
 - a. Determined to be essential to sustain the member's growth within nationally recognized height/weight or BMI (body mass index) levels, maintain health and support metabolic balance
 - b. Obtained only under physician order; and
 - c. Supervised by the member's PCP, attending physician or appropriate specialist for the medical and nutritional management of a member who has:
 - Limited capacity to metabolize typical foods or certain nutrients contained (1) in typical food; or
 - (2) Other specific nutrient requirements as established by medical evaluation.

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- 3. Metabolic formulas ordered for a member must be processed for the specific dietary management of the member's metabolic condition. The formula must meet the member's distinctive nutritional requirements that are established through medical evaluations by the member's PCP, attending physician or appropriate specialist, and/or the metabolic nutritionist.
- 4. Modified low protein foods must be formulated to contain less than one gram of protein per unit or serving. For purposes of this policy, modified low protein foods do not include foods that are naturally low in protein.
- 5. Soy formula is covered only for members receiving Early and Periodic Screening, Diagnosis and Treatment (EPSDT) services and KidsCare members diagnosed with galactosemia and only until they are able to eat solid lactose-free foods.
- 6. Members receiving EPSDT services and KidsCare members receiving diagnosed with a metabolic disorder included in this policy are eligible for services through Children's Rehabilitation Services (CRS).
 - a. Members receiving EPSDT services and KidsCare members must receive metabolic formula through CRS
 - b. Members receiving EPSDT services and KidsCare members who require modified low protein foods receive them through AHCCCS Administration.
- 7. Medical foods must be ordered from a supplier of metabolic formula, modified low protein foods or soy formula that is approved by AHCCCS. Foods purchased through grocery or health food stores are not covered.
- 8. AHCCCS Administration is responsible for providing both necessary metabolic formula and modified low protein foods for members 21 years of age and older who have been diagnosed with one of the inherited metabolic disorders included in this policy.
- 9. Contractors remain responsible for initial and follow-up consultations by a genetics physician and/or a metabolic nutritionist, lab tests and other services related to the provision of medical foods for enrolled members diagnosed with a metabolic disorder included in this policy.

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Approval Process

- 1. Upon completion of the member's initial consultation with a genetics physician and metabolic nutritionist, and the determination of metabolic formula and/or low protein foods necessary to meet the member's nutritional needs, the request is forwarded to the contact person for metabolic nutrition at AHCCCS/Office of Medical Policy and Programs (OMP) for review and processing.
- 2. After review and approval, the AHCCCS/OMP contact person forwards the order to the appropriate supplier to be filled.
- 3. The supplier then completes and ships the order to the member and sends the claim to AHCCS Administration for payment.
- 4. All necessary management and ordering of medical foods are conducted through AHCCCS/OMP. Contractors will be informed of services provided through AHCCCS Administration for enrolled members who are diagnosed with one of the included metabolic conditions, however, all approvals and payments for medical foods are the responsibility of AHCCCS Administration.
- 5. Coordination of payment between AHCCCS Administration, CRS and/or private insurance carriers, as well as communication with the medical food suppliers, will be provided through AHCCCS/OMP.

See Appendix D of this Manual for flow charts addressing the process used in ordering metabolic foods.

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TELEMEDICINE

<u>Description of Benefit.</u> AHCCCS covers medically necessary consultative and/or treatment telemedicine services for all eligible members within the limitations described in this policy when provided by an AHCCCS registered provider.

Definitions.

- 1. <u>Consulting provider</u> means a licensed physician or clinical psychologist who provides an expert opinion to assist in the diagnosis or treatment of a member.
- 2. <u>Hub site</u> means the location of the telemedicine consulting provider which is considered the place of service.
- 3. <u>Medical professional personnel</u>, for the purposes of this policy, include a registered nurse (RN), licensed practical nurse, clinical nurse specialist, RN midwife, registered nurse practitioner, physician assistant, behavioral health case manager, behavioral health professional or an occupational, physical, speech or respiratory therapist.
- 4. <u>Real time</u> means the interactive, two-way transfer of information and medical data, which occurs at two sites simultaneously: the hub site and the spoke site.
- 5. <u>Referring provider</u> means a licensed physician, physician assistant, RN practitioner, RN midwife, or clinical psychologist who arranges a telemedicine consultation to assist in the diagnosis or treatment of a member.
- 6. <u>Spoke site</u> means the location where the member is receiving the telemedicine service
- 7. Store and forward means telecommunications technology for the transfer of medical data from one site to another through the use of a camera, or other similar device, that records (stores) an image which is then sent (forwarded) via telecommunication to another site for teleconsultation. Services delivered using telecommunications technology, but not requiring the member to be present during their implementation, are not considered "telehealth" or "telemedicine". These services would be considered the same as services delivered on-site.

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8. Telemedicine means the delivery of diagnostic, consultation and treatment services that occur in the physical presence of the member on a real time basis through interactive audio, video and data communications, as well as the transfer of medical data on a store and forward basis for diagnostic or treatment consultations.

At the time of service delivery via real time telemedicine, the member's health care provider may designate a trained telepresenter to present the case to the consulting provider if the member's primary care provider or attending physician, or other medical professional who is familiar with the member's medical condition, is not present. The telepresenter must be familiar with the member's medical condition in order to present the case accurately. Medical questions may be passed on to the referring provider when necessary.

Services provided via telemedicine are billed by the consulting provider.

Non-emergency transportation to and from the telemedicine spoke site to receive a medically necessary consultation or treatment service is covered.

For information regarding covered behavioral health services for title XIX and Title XXI members, refer to Appendix G of this manual.

Conditions, Limitations and Exclusions.

Both the referring and consulting providers must be registered with AHCCCS.

A consulting service delivered via telemedicine by other than an Arizona licensed provider must be a single, or infrequent, service provided to a specific member by a physician or clinical psychologist licensed to practice in the state or jurisdiction from which the consultation is provided.

AHCCCS Division of Fee for Service Management does not require prior authorization (PA) for medically necessary telemedicine services performed by fee-for-service (FFS) providers. Refer to Chapter 800 for complete information regarding PA requirements.

Refer to Policy 310 of this Chapter for complete information regarding covered behavioral health services.

Refer to the AHCCCS FFS Provider Manual for complete information regarding billing procedures. This manual is available on the AHCCCS Web site at www.azahcccs.gov.



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HIGH FREQUENCY CHEST WALL OSCILLATION (HFCWO) THERAPY

High Frequency Chest Wall Oscillation therapy (HFCWO) is a form of chest physiotherapy that promotes airway clearance for retained pulmonary secretions. This form of therapy has been shown to be equally as effective as other forms of such therapy, such as postural drainage and clapping (CPT), flutter valve or blow glove, etc., in helping an individual with clearing secretions from the lungs. A HFCWO vest will not replace a percussor, caregiver and/or self-administration of chest physiotherapy unless it is demonstrated that these forms of therapy are no longer effective.

HFCWO requires prior authorization. All cases will be reviewed on a case-by-case basis. Requests for prior authorization must be accompanied by specific documentation in the individual's personal medical record that supports the medical necessity for HFCWO. Criteria for medical necessity include, but are not limited to, all of the following:

- 1. Diagnosis of cystic fibrosis, and
- 2. Documentation of excessive sputum production combined with the member's inability to clear the sputum without assistance, and
- 3. Copy of chest x-ray report and pulmonary function tests showing findings consistent with moderate or severe chronic obstructive pulmonary disease (COPD), and
- 4. Prescription signed by a M.D. or D.O. with a specialty in pulmonary disease, indicating the need for at least daily (or more frequent) chest physiotherapy, and
- 5. Age 2 years or older or 20 inch chest size, whichever comes first, and
- 6. Specific documentation of failure of other, more cost effective, methods of chest physiotherapy, or airway clearance, including CPT and flutter valve, and
- 7. Specific documentation supporting why HFCWO therapy for the member is superior to other more cost-effective therapy methods, including at least one of the following:
 - a. Promotes independent self-care for the individual, or



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- b. Allows independent living or university or college attendance for the individual,
- c. Provides health stabilization in single adults or emancipated individuals without able partners to assist with CPT, or
- d. Severe end-stage lung disease requiring complex or frequent chest physiotherapy.
- 8. Evidence that the member can use the vest effectively, including continuing compliance with all forms of prescribed therapy and treatment and member and family acceptance of HFCWO therapy, and
- 9. Coordination between the provider office or clinic and AHCCCS or other payer source, such as ADHS/CRS or AHCCCS Contractor, prior to implementation of HFCWO therapy for long-term use.

Discontinuation Criteria For HFCWO

Discontinuation criteria for the HFCWO vest include, but are not limited to, the following:

- 1. Patient and /or prescribing physician request
- 2. Patient treatment compliance at a rate of less than 50% usage as prescribed in the medical treatment plan, to be checked at two (2) and six (6) months of usage.

HFCWO For Members Without Diagnosis Of Cystic Fibrosis

HFCWO is a covered service for adult members (age 21 and older) who meet all of the above criteria for medical necessity (except for diagnosis of Cystic Fibrosis), but who have a diagnosis such as chronic bronchiectasis or alpha-1 antitrypsin deficiency where there is an acute exacerbation of the illness or the disease is in the terminal stages. AHCCCS Contractor Medical Directors, or the AHCCCS Medical Director for FFS members, shall perform a case-by-case review to determine that HFCWO therapy is superior to other, more cost effective, forms of therapy. Prior authorization is required.